

Rejection Of Claims Under 35 U.S.C. § 102(e)

Applicants note with appreciation that the Examiner has withdrawn the rejection of claims 135-138 and 153-156 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,517,863 (hereinafter "LaTorre").

Rejection Of Claims Under 35 § 103(a)

As a threshold matter, applicants point out that in the June 3, 2005 Final Office Action the Examiner made two fundamental errors in rejecting the claims under 35 U.S.C. § 103(a). First, the Examiner focused on particular isolated disclosures in applicants' specification to discount the "anhydrous" distinction rather than applying the obviousness analysis to the presently pending claims. Second, the Examiner failed to consider unexpected and surprising results achieved by the presently claimed invention. Each of these issues will be addressed in more detail below.

Claims 135-138 and 153-156

The Examiner rejected claims 135-138 and 153-156 under 35 U.S.C. § 103(a) at the outset repeating nearly verbatim the reasons given in the September 10, 2004 Office Action. The Examiner then responded to applicants' March 7, 2005 Communication in Response to Office Action in which applicants pointed out three significant distinctions between the presently claimed invention and the LaTorre reference. More specifically, applicants pointed out (and again point out) that in sharp contrast to LaTorre, the presently claimed invention (1) works using substantially anhydrous cosmetic formulations; (2) does not require the presence of additional anti-microbial agents; and (3) provides a long duration of effectiveness. While the Examiner ostensibly addressed each of these points in June 3, 2005 Final Office Action, applicants respectfully maintain that the Examiner did not give proper consideration to what is

claimed by applicants and how the claimed invention differs from LaTorre, nor did the Examiner give proper consideration to the unexpected results achieved by the present invention.

Therefore, applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 103(a). More specifically, applicants maintain that claims 135-138 and 153-156 are not obvious over LaTorre. Applicants point out that claims 135 and 153 are the only presently pending independent claims. Claim 135 recites:

A cosmetic composition comprising bioactive glass and a substantially anhydrous cosmetic formulation with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc.

Claim 153 recites:

A method of making a cosmetic composition comprising combining bioactive glass with a substantially anhydrous cosmetic formulation with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc.

Applicants point out that LaTorre does not disclose, teach or suggest the cosmetic compositions or methods of making cosmetic compositions according to the presently claimed invention. There can be no dispute that, in sharp contrast to LaTorre, the present invention (1) works using substantially anhydrous cosmetic formulations; (2) does not require the presence of additional anti-microbial agents; and (3) provides a long duration of effectiveness. Each of these distinctions is addressed below.

Substantially Anhydrous

As specifically recited in independent claims 135 and 153, the presently pending claims require the presence of a substantially anhydrous cosmetic formulation. Since LaTorre does not disclose, teach or suggest a cosmetic composition comprising a substantially anhydrous cosmetic formulation, LaTorre cannot render obvious the presently pending claims.

More particularly, and as stated previously, LaTorre stresses the criticality of using aqueous solutions or hydrophilic (“water-loving”) polymers for the LaTorre invention to work. For instance, LaTorre discloses using either an aqueous solution or, alternatively, a gel based formulation (which uses a hydrophilic polymer) to create a layer of hydroxyapatite or other calcium phosphate mineral on the nail. (Col. 2, lines 48-61.) LaTorre further states that “[a]n effective nail-enhancing amount of bioactive glass is defined as an amount capable of providing the nail surface with at least a thin coating of hydroxyapatite.” (Col. 3, lines 30-33.) LaTorre also states that the theory behind the invention is the “adsorption of hydronium ions from a solution and a release of sodium and/or calcium ions...” (Emphasis supplied.) (Col. 3, lines 38-40.) Thus, aqueous solutions and hydrophilic polymer solutions are critical to LaTorre.

Importantly, LaTorre discloses beyond doubt the criticality (for the LaTorre invention) of aqueous or hydrophilic-based compositions when describing formulations which include bioactive glass. In doing so LaTorre states.

The bioactive glass or extract of bioactive glass may be administered to the nail in a topical formulation, such as in the form of a suspension, lotion, cream (water-in-oil emulsion) or gel, provided that the formulation includes a sufficient amount of water such that the ions can be formed and allowed to react with the nail to form the hydroxyapatite layer. [Emphasis supplied.] [Col. 4, line 62 - Col. 5, line 3.]

Example 1 in LaTorre (the only example in which an arguably cosmetic formulation comprising bioactive glass is described), used an equal volume of bioactive glass and water to form a paste. (See Col. 6, lines 45-62.) No example describes a substantially anhydrous cosmetic formulation or method.

Furthermore, since LaTorre unequivocally teaches the criticality of aqueous solutions and hydrophilic polymer solutions, it is impossible that the Examiner’s rejection can meet the

“reasonable expectation of success” requirement which, *inter alia*, is necessary for any obviousness finding to stand. Since LaTorre teaches away from using substantially anhydrous cosmetic formulations there is no expectation of success possible based on the teaching of LaTorre, much less a reasonable one.

In the June 3, 2005 Final Office Action the Examiner did not dispute that LaTorre teaches the criticality of hydrophilic, water-based formulations. The Examiner simply asserted that “the instant invention when taken as whole, would have been *prima facie* obvious.” The Examiner’s citation to portions of applicants’ specification, rather than the pending claims, suggests that the Examiner believes that “the invention as whole” analysis can be based on the specification as a whole and that piecemeal selections from the specification are relevant to that analysis. The MPEP, however, instructs otherwise and confirms that the relevant standard is whether the claimed invention taken as a whole would have been obvious. For the reasons stated herein, applicants’ claimed invention, taken as a whole, with proper consideration given to the substantially anhydrous limitation of the claims, is not obvious. (See MPEP 2141.02). The Examiner’s reliance on isolated portions of the specification, rather than the claim elements, highlights the lack of adherence to the MPEP on this issue.

The distinction between what is claimed and what is disclosed in an obvious analysis is a very important point. Indeed, in the instant case, it is dispositive. The obviousness analysis must address what is claimed, not what is disclosed. The MPEP clearly explains that one of the key inquiries in an obviousness analysis is the difference between the prior art and the claims in issue. (See, e.g., MPEP §§ 706.02(j) and 2141; see also *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) So there can be no dispute, applicants are not claiming in the instant application (as distinct from any future continuation or divisional applications) all of the many

formulations which they have disclosed. Rather, applicants are presently claiming compositions and methods comprising bioactive glass and a substantially anhydrous cosmetic formulation.

Since LaTorre does not teach or suggest substantially anhydrous cosmetic compositions and methods, and, in fact, teaches the opposite, it should be abundantly clear that LaTorre cannot render obvious the currently pending claims.

No other basis for non-obviousness is necessary; for the sake of completeness, however, applicants will again discuss additional bases for the non-obviousness of claims 135-138 and 153-156.

Does Not Require The Presence Of Additional Anti-Microbial Agents

LaTorre also concedes the need for additional anti-microbial additives to provide a significant anti-microbial effect as explained in applicants' March 7, 2005 Communication. In contrast, the presently claimed invention provides significant anti-microbial properties without the use of anti-microbial additives.

In the June 3, 2005 Final Office Action the Examiner did not dispute that LaTorre teaches the need for additional anti-microbial additives. Rather, the Examiner stated that "[t]he instant 'comprising' claim language permits the presence of additional components or ingredients aside from those instantly recited in the claims." Applicants respectfully point out that the Examiner's statement is not relevant to unexpected and surprising results. In other words, whether or not the "comprising" language permits the inclusion of other ingredients, it is a surprising and unexpected result of the present invention that the formulations work without including antimicrobials. This is a significant unexpected and surprising result that, *inter alia*, saves both the cost of anti-microbials and the time that would be required for incorporating anti-microbials into a cosmetic formulation.

Accordingly, in view of this unexpected and surprising result, applicants maintain that LaTorre does not render obvious claims 135-138 or 153-156.

Long Duration Of Effectiveness

LaTorre also does not disclose stable cosmetic compositions (or methods of making such compositions) comprising bioactive glass and a substantially anhydrous cosmetic formulation.

Rather, LaTorre discloses that:

It is preferable that the glass not be significantly prereacted prior to application to the nails. This can be achieved, for example, by mixing the bioactive glass and water to form the compositions and applying the composition to the nails immediately after mixing. [Emphasis supplied.] [Col. 5, lines 52-56.]

In contrast, the presently claimed invention provides stable compositions (and methods of making same) comprising bioactive glass and a substantially anhydrous cosmetic formulation. Such compositions have an extended duration of effect and, unlike LaTorre, do not need to be used immediately upon combination.

In the June 3, 2005 Final Office Action the Examiner did not dispute that LaTorre fails to teach stable cosmetic compositions (or method of making such compositions). Rather, the Examiner stated that “the prior art cosmetic formulations evidence that the silver, copper or zinc ions are not detrimental to cosmetic products.” Applicants are not at all clear about the “prior art” to which the Examiner refers. In the June 3, 2005 Final Office Action, only LaTorre and U.S. Patent No. 6,224,888 (“Vatter”) were cited, neither of which refer to these metal ions. It appears that the Examiner may be referring to U.S. Patent No. 5,290,544 (“Shimono”). Shimono, however, was not cited by the Examiner in the September 10, 2004 Office Action or the June 3, 2005 Final Office Action.

In any event, none of these references (including Shimono) teaches or suggests a cosmetic composition comprising bioactive glass and a substantially anhydrous cosmetic formulation which provides an extended duration of effect and, unlike LaTorre, does not need to be used immediately upon combination. And as explained above, none of the references describe a composition that works without the inclusion of anti-microbials (whether those described by LaTorre or the metal ions described by Shimono), much less a composition that is stable and substantially anhydrous.

Accordingly, in view of this further unexpected and surprising result, applicants maintain that LaTorre does not render obvious claims 135-138 or 153-156.

Claims 139-152 and 157-170

In the June 3, 2005 Final Office Action, the Examiner again rejected claims 139-152 and 157-170 under 35 U.S.C. § 103(a) as being allegedly unpatentable over LaTorre in view of Vatter.

In response, applicants respectfully traverse the Examiner's rejection under § 35 U.S.C. 103(a). Applicants maintain that claims 139-152 and 157-170 are not rendered obvious by LaTorre in view of Vatter. The Examiner relies on Vatter simply for its recitation of cosmetic additives. The Examiner stated that Vatter cures the deficiencies of LaTorre with respect to various additives. Importantly, however, the Examiner did not state that Vatter cures the specific deficiencies of LaTorre discussed in detail above, namely the anhydrous cosmetic formulation limitation along with unexpected and surprising results. It is not disputed (and cannot be disputed) that Vatter fails to cure those deficiencies.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 139-152 and 157-170 under 35 U.S.C. § 103(a) over LaTorre in view of Vatter.

Conclusion


In view of the foregoing, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the June 3, 2005 Final Office Action and allow the presently pending claims, namely claims 135-170.

No fee is believed to be necessary in connection with the filing of this Communication. If any additional fee is necessary applicants hereby authorize such fee to be charged to Deposit Account No. 50-0540.

If a telephone interview would be of assistance in advancing the prosecution of this application, applicants' undersigned attorney encourages the Examiner to telephone him at the number provided below.

Respectfully submitted,

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